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Section 2: Summary of Safety and Effectiveness

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Neurosign 800 Motor Nerve Monitor

The Neurosign 800 is an EMG machine and nerve stimulator. The machine consists of a central control unit to which a pre-amplifier pod and intramuscular or surface electrodes are attached for EMG recordings. Additionally connected to the main unit is a stimulator pod to which a stimulating probe which delivers current to nerve tissue may be connected.

The Neurosign 800 is intended to monitor and to stimulate cranial motor nerves. The motor nerves are monitored by detecting EMG activity in the muscles they innervate.

The Neurosign 800 is similar to the following products which are currently in commercial distribution:

- a) Neurosign 100, The Magstim Company
- b) Brackmann II, WR Medical
- c) NIM-2XL Nerve Integrity Monitor, Xomed

The safety and effectiveness of the Neurosign 800 has been established through various techniques. The history of the similar products listed above lacks complaints related to safety and effectiveness, and as far as we are aware there have been no reports of adverse effects or reportable incidents connected with them, or in any published papers on nerve monitoring.

The Magstim Company performs extensive in-house and on-site clinical evaluation of all its products both prior to and after product release for distribution. Our methods and procedures for acceptance of products as well as our techniques for clinical evaluation are performed using team participation. Team members include, but are not limited to, Marketing, Manufacturing, Engineering, Clinical Engineering, Manufacturing Engineering and Quality Assurance. The Neurosign 800 has met all specifications and expectations for its intended use based on the evaluations conducted thus far.

The materials and methods used to manufacture the Neurosign 800 do not vary from the current materials and methods used by The Magstim Company in the manufacture of the Neurosign 100. We will incorporate new proven technologies as they become available; however, these improvements support product performance through greater reliability.

The Magstim Company concludes that the Neurosign 800 is safe and effective for its intended use.